REMARKS

Claims 1-4, 6, 14-16, 29-30 are currently pending. Claims 8, 10-13, 17-28 are withdrawn and 5, 7, and 9 are cancelled.

Claim 1 was amended to delete thienyl from R1, (a-4) and (a-5) from R3, R11 in view of deletion of (a-4), and (c-9) and (c-10) from Z in view of the Patent Office's position concerning enablement under 35 USC § 112., first paragraph, which is not agree with. In addition,7 -benzoyl-3-methyl-2(1H)-quinoxalinone is also excluded from claim 1 in view of Ali.

Enablement Rejection

Claims 1-3, 6, 14-15, and 29-30 stand rejected under 35 USC §112, first paragraph, on the asserted grounds that the specification, while being enabling for certain substituents corresponding to Formula (I), does not "reasonably" provide enablement for the "R^1 is thienyl and R^3 is $-S-R^{11}$, -CN, or heterocyclic ring systems other than formulae (c-1), (c-2), (c-3) and (c-4), which have additional substitutions." (Office Action at page 3.)

The Applicants respectfully traverses this rejection.

While not agreed with, claim 1 was amended to delete thienyl from R1, (a-4) and (a-5) from R3, R11 in view of deletion of (a-4), and (c-9) and (c-10) from Z in view of the Patent Office's position concerning enablement under 35 USC § 112., first paragraph.

The Patent Office bears the initial burden of providing reasons for doubting the objective truth of the statements made by the Applicants. Only when the Patent Office meets this burden does the burden shift to Applicants to provide suitable evidence indicating that the specification is enabling in a manner commensurate in scope with the protection sought by the claims. Because the Patent Office has failed to make a prima facie case for rejecting the claims for the reasons set forth below, the burden has not shifted and it still remains with the Patent Office.

For this rejection, the Office Action relied upon the holding of *In re Wands* (858 F.2d 731, 737; 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), which sets forth the factors to be considered in determining whether a conclusion of "undue experimentation" is appropriate. While not every factor is relevant for every enablement determination, the analysis in the Office Action must consider all of the evidence related to each factor and

any conclusion of enablement must be based on the evidence as a whole. It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the factors while ignoring one or more of the others.

As Z being (c-5), attention is directed to compound 16 and (c-11) attention is directed to compound 7. Based on the foregoing, it is believed that (c-5) and (c-11) are fully enabled.

Concerning the heterocyclic meanings for Z, the Z definition is directed to 11 specific ring structures of which 6 are supported by working examples. Furthermore, the working examples described in the specification show that at least there is some degree of variation possible within the Z definition. For instance, the working examples show that Z may represent a 5 or 6 membered heterocycle or that it may be saturated or not saturated or that it may contain one or more heteroatoms or that it may be unsubstituted or substituted. Furthermore, general synthesis protocols to obtain these compounds are described in the specification. Based on this, (c-6), (c-7), (c-8) are also fully enabled.

It is respectfully requested that the rejection be withdrawn for the reasons set forth above.

Anticipation Rejection

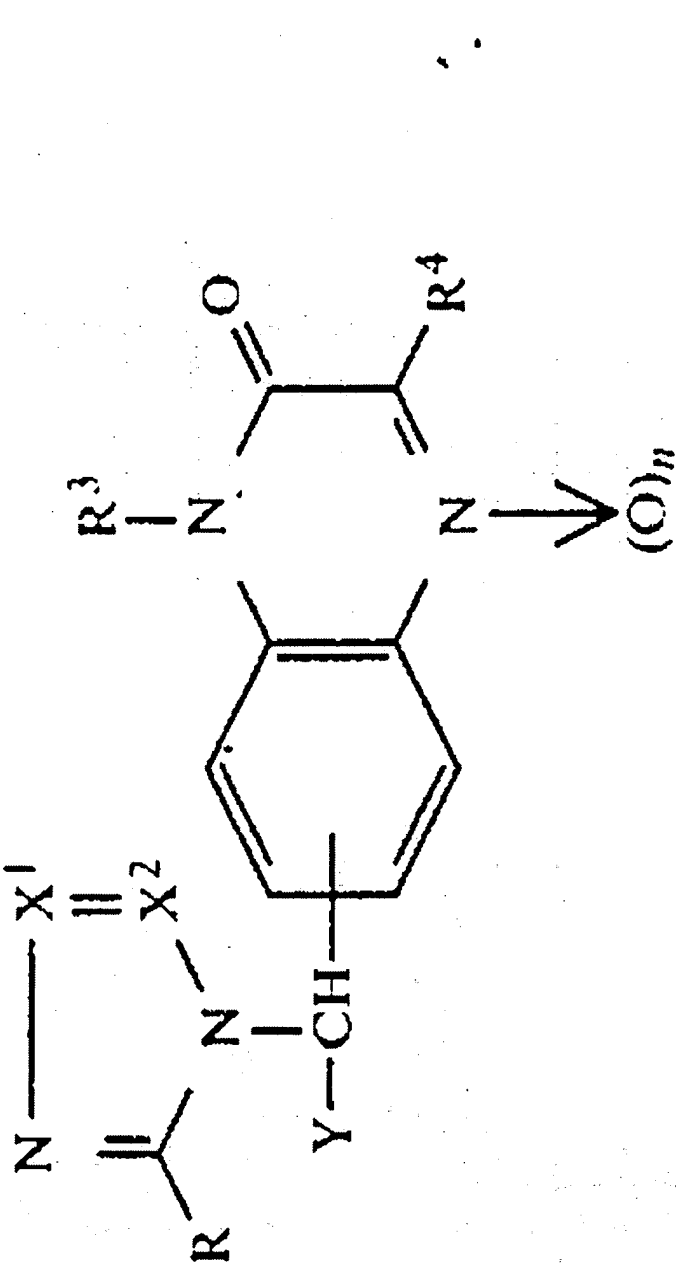
Claims 1-3, 6, 14-15, and 29-50 were rejected under 35 USC § 102(b) as being anticipated by US Pat. No. 5,028,606 (the "'606 Patent"). (Office Action at page 6.)

For the reasons set forth below, the rejection is respectfully traversed.

The '606 Patent discloses various compounds of the following formula and in the Table 9 that were specifically enumerated int eh Office Action at pages 7-8.

y

TABLE 9



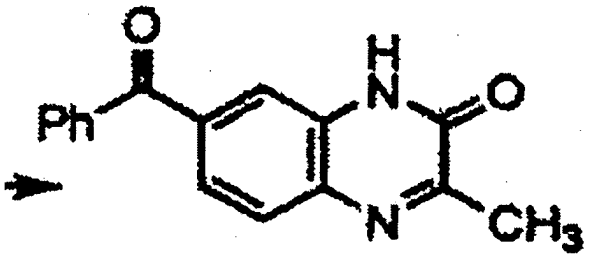
As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall,* 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984)

Initially, we note that claim 1 includes a proviso that when n is 0, X is N, R^1 is C_{1-6}alkyl, R^2 is hydrogen, R^3 is a group of formula (b-1), t is 0, Z is the heterocyclic ring system (c-2) wherein said heterocyclic ring system Z is attached to the rest of the molecule with a nitrogen atom, and R^{12} is hydrogen; then at least one of the substituents R^4, R^5 or R^6 is other than hydrogen, halo, C_{1-6}alkyl or C_{1-6}alkyloxy. It is believed that this proviso removes any of the infirmities of the claims set forth in the Office Action vis-à-vis the '606 patent. For this reason alone, the rejection should be withdrawn.

Claims 1 and 29 were rejected as being anticipated by Ali et al, *Molecules* 5:864-873 (2000) ('Ali").

For the reasons set forth below, the rejection is respectfully traversed.

Ali discloses various compounds, including



1b

on page 865.

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall,* 198 USPQ 344, 346 (CCPA 1978); *Lindemann*

Maschinenfabrik GMBH v. American Hoist and Derrick Co., 221 USPQ 481, 485 (Fed. Cir 1984)

Initially, we note that claim 1 was amended to exclude 7-benzoyl-3-methyl-2(1H)-quinoxalinone. Given this exclusion from claim 1, it is believed that this rejection is moot and should be withdrawn.

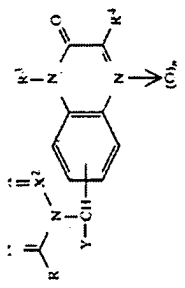
In addition, it is noted that the instant rejection makes reference to "Cushman *et al.*" It is not known what Cushman is, but it is presumed that this is an artifact carried-over from a different office action. Clarification is requested.

Obviousness Rejection

Claims 4 and 16 were rejected under 35 USC §103(a) as being unpatentable over the "606 Patent, in view of Wolff (Burger's Medicinal Chemistry, 4th ed., pp. 336-337 (1980)). (Office Action at 10.)

For the reasons set forth below the rejection, respectfully is traversed.

The '606 Patent discloses



Comp. No.	Ex. No.	R	$-X^1=X^2-$	Y	p	R^1	R^4	n	mp(°C.)/ base/salt
57	20	H—	—CH=CH—	C_6H_5—	6	H—	CH_3—	0	254.0
58	20	H—	—CH=CH—	H—	7	H—	CH_3—	0	297.6
59	20	H—	—CH=CH—	H—	6	H—	CH_3—	0	271.3
60	20	H—	—CH=CH—	C_6H_5—	7	H—	CH_3—	0	218.4

. Of particular interest is compound 60 of Table 9 of the "606 Patent.

In making the rejection, the Office Action asserted that

> The difference between the instant compound and that of the prior art is that the instant compound has ethyl groups instead of methyl groups in the positions 7 and 3 of quinoxalinone ring.

The Office Action reasoned that

> It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute methyl group with ethyl group since it is routine experimentation to substitute one C_{1-5} alkyl group with another C_{1-5} alkyl group in the field of medicinal chemistry. To those skilled in the art of medicinal chemistry, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members.

(Office Action at page 10.)

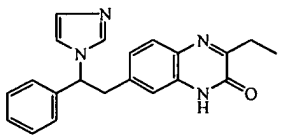
The Office Action relies on Wolff as follows:

> of obtaining compounds which could be used in pharmaceutical compositions. However, the examiner provides Wolff's reference. Wolff teaches that the addition of alkyl groups to active pharmacological agents often improves activity and bioavailability by increasing lipophilicity (see the examples in Table 8.2, p. 337 of a local anesthetic SAR). As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare homologues of compounds taught by US 5,028,606, with longer alkyl chains, as suggested by Wolff, to achieve better bioavailability or to improve activity.

The Office Action then concluded that "one of ordinary skill in the art would have been motivated to prepare homologues of the compounds taught in the references with

the expectation of obtaining compounds, which could be used in pharmaceutical compositions. (Office Action at page 11.)

Initially, it is noted that claim 4 (and claim 16 because it depends from claim 4)



includes compound 1 . The compound relied on in the instant rejection of the '606 Patent is characterized by an imidazolyl moiety bound to a carbon atom, which is then directly bound to the quinoxalinone ring.. As seen above, Compound 1 of claim 4 (and claim 16) contains an additional carbon atom between the imidazolyl carrying carbon atom and the quinoxalinone ring. Thus it is respectfully submitted that the claimed compound and the cited compound are not homologues of each other. It is submitted that is is not a simple routine replacement of a methyl by ethyl. The indication position concerns a linker between the quinoxalinone ring and the phenyl ring. There is no indication in the '606 Patent that an extra carbon atom may be inserted between the imidazolyl carrying carbon atome and the quinoxalinone moiety while maintaining a pharmacologically active compound. It is submitted that the '606 Patent does not teach or suggest any degree of freedom for this modification as the Z substituent of the '606 Patent is always directly linked to the carbon atom carrying the imidazolyl. Table 8.2 of Wollf does not close this gap at the variability of the alkyl in the R group disclosed therein is not a linker between two ring structures. For these reasons, it is submitted that the rejection is improper and should be withdrawn.

Obviousness-type Double Patenting

Claims 1-4, 6, 14-16, and 29-30 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Office Action at page 12.) The Office Action alleged that claims1-4, 6, 14-16, and 29-30 of the captioned application "are unpatentable over claims 1, 2, and 7 of co-pending US Patent Application No. 10/595.891 in view of the '606 Patent. The Office Action did not indicate that the rejected claims are otherwise allowable. Upon notification in the Office Action that claims 1-4, 6, 14-16, and 29-30 are allowable but for this rejection, the substance of this rejection will be addressed.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Accordingly, entry of the claims and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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